DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
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June 20, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David J. Gury
Chairman, President and CEO
Nabi
5800 Park of Commerce Boulevard NW
Boca Raton, Florida 33487

Ref. # - DEN-00-27

Dear Mr. Gury:

During an inspection of Nabi Biomedical Center, located at 301 Second Street SW, Albuquerque, New Mexico, on March 15 through March 30, 2000, our investigator documented that yo ir firm violated Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680, as follows:

1. Your firm failed to adequately quarantine viral reactive units from non-reactive units in freezer storage per your procedures (21 CFR 606.40 (a)(6)). For example, our review of your firm's flow logs indicated that all reactive units were not put on hold. Our inspection revealed that two units listed as placed on hold could not be located in the quarantine locker.

2. Your firm failed to adequately segregate units pending the completion of tests, per your procedures (21 CFR 606.40 (a)(3)). For example, our review of units in your freezer determined that unit # [illegible] and unit # [illegible] were to be quarantined and destroyed, but were found commingled with other tested units in the freezer.

3. Your firm failed to maintain adequate records showing the status/disposition of reactive units (21 CFR 606.160 (b)(3)(i)). For example, our review of your records found several instances where records indicate the units were shipped to waste, however, our investigator found the units were either in the quarantine locker or were commingled with units awaiting test results. Also, our investigator's review of your firm's flow logs found many were still incomplete long after the units were drawn.

4. Your firm failed to follow standard operating procedures in that donors were not deferred who had indicated they cohabitated with viral reactive persons and look-back procedures were not performed (21 CFR 606.100(b)(1)).

5. Your firm's record system is not adequate to screen donors when determining donor suitability and your firm failed to follow procedures regarding donor identification (21 CFR 606.100 (b)(1) and 606.160 (b)). For example, review of your donor history files found that donors are issued a new donor number if they have not donated in the previous 6 months. The interviewer does not document the date of the last donation or if the donor had donated under a different name. Since your system is a manual system, it is difficult, if not impossible, to manually search all the records required to insure that duplicate records exist. Also, your firm allowed a donor to donate with an out-of-state driver's license, even though your procedures state, "Only donors with local addresses of a non-transient nature will be accepted." This donor was subsequently found to be HCV reactive.

We are in receipt of your correspondence dated April 18, 2000, signed by Dr. Pinya Cohen, in response to the deficiencies noted on the March 30, 2000, form FDA 483. In response to item #5.1, Dr. Cohen states that your procedures would be able to detect unsuitable donors who fail to admit to previous donations by checking the permanent deferral file and the NDDR and by asking the donor to confirm his or her name and address. However, we are concerned that using a manual system, you will not be able to detect a deferred donor who has undergone a name change since the previous donation.

Although this response indicates that you have re-trained your employees and have conducted reviews of your facilities' operations, we are aware of similar violations found in previous inspections of your firm. Specifically, in 1997 our inspection revealed that your firm failed to adequately segregate reactive units from non-reactive ones. It also found that viral reactive units were not promptly disposed of by your firm. In an April 11, 1997, response to that inspection, Dr. Cohen promised corrections would also be implemented.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your firm is in compliance with all requirements of the federal regulations. We expect that the corrective actions outlined in your April 18, 2000, correspondence have been fully implemented and will assess the adequacy of your corrective actions at a follow-up inspection.

If you fail to correct these deviations immediately, we may take regulatory action. Such action includes license suspension and/or revocation, seizure and/or injunction.

If you have any questions, please feel free to contact Ms. Regina A. Barrell, Compliance Officer, Food and Drug Administration, Denver District, P. O. Box 25087, Denver, Colorado 80225, or by phone at (303) 236-3043.

Sincerely,

Thomas Allison
District Director

Enclosure: FDA 483

cc: Pinya Cohen, Ph.D.
Vice President
Regulatory Affairs
5800 Park of Commerce Blvd. NW
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Mr. Curtis Chambers
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